Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (Text with EEA relevance)

COMMISSION REGULATION (EU) No 257/2010

of 25 March 2010

setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(1)], and in particular Article 32 thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1333/2008 requires the Commission to set up a programme for the re-evaluation, by the European Food Safety Authority (hereinafter referred to as 'EFSA'), of the safety of food additives that were already permitted in the Union before 20 January 2009.

(2) In 2007, the Commission presented a report to the European Parliament and the Council on the progress of the re-evaluation of food additives[(2)]. That report provides a summary of the recent additive re-evaluations undertaken by the Scientific Committee on Food ('SCF') and EFSA and describes the related actions taken by the European Commission on the basis of the scientific opinions.

(3) The re-evaluation of food colours has already been started with priority, since these food additives have the oldest evaluations by the SCF. The re-evaluation of certain colours (namely E 102 Tartrazine, E 104 Quinoline Yellow, E 110 Sunset Yellow FCF, E 124 Ponceau 4R, E 129 Allura Red AC and E 122 Carmoisine, E 160d lycopene) has already been completed. In addition, some food additives such as E 234 Nisin and E 214–219 Para-hydroxybenzoates were re-evaluated in recent years since new scientific data was requested or became otherwise available. As a consequence, those additives do not need to be re-evaluated again.

(4) Taking into account that sweeteners have the most recent evaluations they should be re-evaluated the last.

(5) The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the SCF or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU[(3)] of 2001. The report 'Food additives in Europe 2000[(4)]' submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation.

(6) For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong. EFSA should however be in a position to start the re-evaluation of a food additive or a group of food additives with higher priority, on a request from the Commission or on its own initiative, if new scientific evidence emerges that indicates a possible risk for human health or which in any way may affect the assessment of the safety of a food additive.

(7) Deadlines for the re-evaluation should be established in accordance with that order of priorities. In duly justified cases and only when such re-evaluation may delay substantially the re-evaluation of other food additives, the deadlines laid down in this Regulation may be revised.

(8) More specific deadlines for individual food additives or groups of food additives may be set in the future, in order to allow the smooth running of the re-evaluation process or in case of emerging concern.

(9) In order for the re-evaluation procedure to be effective, it is important that EFSA acquires from the interested parties all data relevant to the re-evaluation and that the interested parties are informed well in advance when additional data is necessary for the completion of the re-evaluation of a food additive.

(10) Business operators interested in the continuity of the approval of a food additive under re-evaluation should submit any data relevant to the re-evaluation of the food additive. Where possible, business operators should take steps to submit information collectively.

(11) EFSA should make public one or more open calls for data on all food additives to be re-evaluated. Any technical and scientific information about a food additive which is necessary for its re-evaluation, in particular toxicological data and data relevant for the estimation of the human exposure to the relevant food additive, should be submitted by the interested parties to EFSA within the set time limits.

(12) The food additives to be re-evaluated by EFSA have been previously assessed for their safety by the SCF and many of them have been used since long time. The information to be submitted for their re-evaluation should include existing data on which the previous evaluation of a food additive was based and any new data relevant to the food additive made available since its last evaluation by the SCF. That information should be as comprehensive as possible in order to allow EFSA to complete its re-evaluation and form an up-to-date opinion and should be submitted following to the extent possible

the applicable guidance on submissions for food additive evaluations (currently the guidance established by the SCF on 11 July 2001[5]).

(13) EFSA may require additional information in order to complete the re-evaluation of a food additive. In that case EFSA should request the necessary data in good time either by an open call for data or by contacting the parties that submitted data on the food additive. The interested parties should submit the requested information within a time period that is set by EFSA having considered, where relevant, the views of the interested parties.

(14) Regulation (EC) No 1333/2008 provides that the approval of food additives should also take into account environmental factors. Therefore, in the framework of the re-evaluation of a food additive the interested parties should inform the Commission and EFSA of any information relevant to any environmental risks from the production, use or waste of that additive.

(15) Where the requested information necessary for the completion of the re-evaluation of a particular food additive is not provided, the food additive may be removed from the Union list of approved food additives.

(16) The re-evaluation procedure of food additives must fulfil transparency and public information requirements while guaranteeing the confidentiality of certain information.

(17) By the date of entry into force of this Regulation, the Commission will make available to the public a list of approved food additives that are being re-evaluated with the date of their latest evaluation by the 'SCF' or EFSA.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1 This Regulation sets up a programme for the re-evaluation by the European Food Safety Authority (hereinafter referred to as 'EFSA') of approved food additives, as provided for in Article 32 of Regulation (EC) No 1333/2008.

2 Approved food additives, for which the re-evaluation by EFSA is already completed at the time of the adoption of this Regulation, shall not be re-evaluated again. Those food additives are listed in Annex I.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'approved food additive' means a food additive authorised before 20 January 2009 and listed in Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs[(6)], Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs[(7)] or in Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners[(8)];

(b) 'business operator' means any natural or legal person responsible for ensuring that the requirements of Regulation (EC) No 1333/2008 are met within the food business under its control;

(c) 'interested business operator' means a business operator interested in the continuity of the authorisation of one or more approved food additives;

(d) 'original dossier' means a dossier on the basis of which the food additive was evaluated and permitted for use in food before 20 January 2009.

Article 3

Priorities for the re-evaluation of approved food additives

1 Approved food additives shall be re-evaluated in the following order and within the following deadlines:

a the re-evaluation of all approved food colours listed in Directive 94/36/EC shall be completed by 31 December 2015;

b the re-evaluation of all approved food additives other than colours and sweeteners listed in Directive 95/2/EC shall be completed by 31 December 2018;

c the re-evaluation of all approved sweeteners listed in Directive 94/35/EC shall be completed by 31 December 2020.

2 For certain food additives within the functional classes referred to in paragraph 1 more specific deadlines are set out in Annex II to this Regulation. Those food additives shall be evaluated first among the other food additives of the same functional class.

3 By way of derogation from paragraphs 1 and 2, EFSA may at any moment start the re-evaluation of a food additive or a group of food additives with priority, on a request from the Commission or on its own initiative, if new scientific evidence emerges that

a indicates a possible risk for human health or

b may in any way affect the safety assessment of that food additive or group of food additives.

Article 4

Re-evaluation procedure

When re-evaluating an approved food additive, EFSA shall:

(a) examine the original opinion and the working documents of the Scientific Committee on Food ('SCF') or EFSA;

(b) examine, where available, the original dossier;

(c) examine the data submitted by the interested business operator(s) and/or any other interested party;

(d) examine any data made available by the Commission and Member States;

(e) identify any relevant literature published since the last evaluation of each food additive.

Article 5

Call for data

1 In order to acquire the data from the interested business operators and/or other interested parties, EFSA shall make open call(s) for data for the food additives under re-evaluation. In specifying the timetable for data submission, EFSA shall allow a reasonable time period after the entry into force of this Regulation, to allow the interested business operator and/or any other interested party to meet this duty.

2 The data referred to in paragraph 1 may comprise among others:

a study reports from the original dossier as evaluated by the SCF or EFSA or the Joint FAO/WHO Expert Committee on Food Additives (JECFA),

b information on the data on the safety of the food additive concerned not previously reviewed by the SCF or the JECFA,

c information on the specifications of the food additives presently in use, including information on particle size and relevant physicochemical characteristics and properties,

d information on the manufacturing process,

e information on analytical methods available for determination in food,

f information on the human exposure to the food additives from food (e.g. consumption pattern and uses, actual use levels and maximum use levels, frequency of consumption and other factors influencing exposure),

g reaction and fate in food.

Article 6

Submission of data

1 The interested business operator(s) and any other interested party shall submit the data related to the re-evaluation of a food additive as referred to in Article 5(2), within the period set by EFSA in its call for data. In the submission the interested business operator and the other interested parties shall include the data requested by EFSA by following, to the extent possible, the applicable guidance on submissions for food additive evaluations[(9)].

2 Where there are several interested business operators they may, when possible, submit the data collectively.

3 If during the re-evaluation additional information considered to be relevant for the re-evaluation of a particular food additive is needed, EFSA shall request from the interested business operators, and shall invite other interested parties, to submit this information by an open call for data. It shall set a deadline within which that information shall be submitted having considered, where relevant, the interested business operator's and/or other interested parties' view of the time required. In such cases, EFSA shall make the request for the additional information well in advance so that the overall deadlines for the re-evaluation as set out in Article 3(1) and in Annex II are not affected.

4 Information which has not been submitted within the deadline set by EFSA shall not be taken into account in the re-evaluation. However, in exceptional cases, EFSA may decide with the agreement of the Commission to take into account information submitted after the deadline, if that information is significant for the re-evaluation of a food additive.

5 Where the requested information has not been submitted to EFSA within the set deadlines, the food additive may be removed from the Union list in accordance with the procedure laid down in Article 10.3 of Regulation (EC) No 1333/2008[10].

Article 7

Other information

In the framework of the re-evaluation of a food additive, the interested business operator(s) or any other interested party shall inform EFSA and the Commission of any information available in relation to any environment risks from the production, use or waste of that food additive.

Article 8

Confidentiality

1 Confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties.

2 Information relating to the following shall not, in any circumstances, be regarded as confidential:

a the name and address of the interested business operator;
b the chemical name and a clear description of the substance;
c information for the use of the substance in or on specific foodstuffs or food categories;
d information that is relevant to the assessment of the safety of the substance;
e the method(s) of analysis in food.

3 For the purposes of paragraph 1, the interested business operator(s) and the other interested parties shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification shall be given in such cases.

4 On a proposal from EFSA, the Commission shall decide after consulting the interested business operator and/or the other interested parties which information may remain confidential and shall notify the EFSA and the Member States accordingly.

5 The Commission, EFSA and the Member States shall, in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[11], take the necessary measures to ensure appropriate confidentiality of the information received under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

6 The implementation of paragraphs 1 to 5 shall not affect the circulation of information between the Commission, EFSA and the Member States.

Article 9

Monitoring progress

Every year in December, EFSA shall inform the Commission and the Member States on the progress of the re-evaluation programme.

Article 10

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 March 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX I

A LIST OF APPROVED FOOD ADDITIVES WHICH WERE APPROVED BEFORE 20 JANUARY 2009 AND FOR WHICH THE RE-EVALUATION BY EFSA IS COMPLETED AT THE TIME OF ADOPTION OF THIS REGULATION

E No	Substance	Year of latest evaluation by SCF or EFSA	Status of re-evaluation by EFSA
E 102	Tartrazine	2009	Re-evaluation completed on 23 September 2009
E 104	Quinoline Yellow	2009	Re-evaluation completed on 23 September 2009
E 110	Sunset yellow FCF, Orange Yellow S	2009	Re-evaluation completed on 24 September 2009
E 122	Azorubine, Carmoisine	2009	Re-evaluation completed on 24 September 2009
E 124	Ponceau 4R, Cochineal Red A	2009	Re-evaluation completed on 23 September 2009
E 129	Allura Red AC	2009	Re-evaluation completed on 23 September 2009
E 160d	Lycopene	2008	Re-evaluation completed on 30 January 2008
E 234	Nisin	2006	Re-evaluation completed on 26 January 2006
E 173	Aluminium	2008	Re-evaluation completed on 22 May 2008
E 214	Ethyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004
E 215	Sodium ethyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004
E 218	Methyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004

E 219	Sodium methyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004
E 235	Natamycin	2009	Re-evaluation completed on 26 November 2009
E 473	Sucrose esters of fatty acids	2006	Re-evaluation completed on 23 November 2004; revised on 26 January 2006
E 474	Sucroglycerides	2006	Re-evaluation completed on 23 November 2004; revised on 26 January 2006
E 901	Beeswax, white and yellow	2007	Re-evaluation completed on 27 November 2007

ANNEX II

Specific priorities for certain food additives within the functional classes of food additives as referred to in Article 3(1) and (2)

PART I:

FOOD COLOURS

Within the overall deadline of 31.12.2015 set for the re-evaluation of food colours in Article 3(1) the following specific deadlines are set for the following food colours:

1. **The following food colours shall be evaluated by 15.4.2010**

E 123	Amaranth,
E 151	Brilliant Black BN, Black PN
E 154	Brown FK,
E 155	Brown HT and
E 180	Litholrubine BK

2. **The following food colours shall be evaluated by 31.12.2010**

E 100	Curcumin,
E 127	Erythrosine,
E 131	Patent Blue V,
E 132	Indigotine, Indigo carmine
E 133	Brilliant Blue FCF,
E 142	Green S,
E 150a	Plain caramel,

E 150b	Caustic sulphite caramel,
E 150c	Ammonia caramel,
E 150d	Sulphite ammonia caramel,
E 161b	Lutein,
E 161g	Canthaxanthin,
E 170	Calcium carbonate,

3. **The following food colours shall be evaluated by 31.12.2015**

E 101	(i) Riboflavin (ii) Riboflavin-5'-phosphate,
E 120	Cochineal, Carminic acid, Carmines
E 140	Chlorophylls and Chlorophyllins: (i) Chlorophylls (ii) Chlorophyllins,
E 141	Copper complexes of Chlorophylls and Chlorophyllins: (i) Copper complexes of chlorophylls (ii) Copper complexes of chlorophyllins,
E 153	Vegetable carbon,
E 160b	Annatto, bixin, norbixin
E 160a	Carotenes: (i) mixed carotenes, (ii) beta-carotene,
E 160c	Paprika extract, capsanthin, capsorubin,
E 160e	Beta-apo-8'-carotenal (C30),
E 160f	Ethyl ester of beta-apo-8', -carotenoic acid (C30),
E 162	Beetroot red, betanin,
E 163	Anthocyanins,
E 171	Titanium dioxide,
E 172	Iron oxides and hydroxides,
E 174	Silver,
E 175	Gold

PART II:

FOOD ADDITIVES OTHER THAN COLOURS AND SWEETENERS

Within the overall deadline of 31.12.2018 set for the re-evaluation of food additives other than colours and sweeteners in Article 3(1), the following specific deadlines are set for certain food additives and groups of food additives:

1. **Preservatives and antioxidants E 200-203; E 210-215, E 218-252, E 280-285; E 300-E 321 and E 586 shall be evaluated by 31.12.2015**

with higher priority within this group on:

E 310-312	Gallates
E 320	Butylated hydroxyanisole (BHA)
E 321	Butylated hydroxytoluene (BHT)
E 220-228	Sulphur dioxide and sulphites
E 304	Fatty acid esters of ascorbic acid: (i) Ascorbyl palmitate (ii) Ascorbyl stearate
E 200-203	Sorbic acid and sorbates
E 284	Boric acid
E 285	Sodium tetraborate (borax)

E 239	Hexamethylene tetramine
E 242	Dimethyl dicarbonate
E 249	Potassium nitrite
E 250	Sodium nitrite
E 251	Sodium nitrate
E 252	Potassium nitrate
E 280-283	Propionic acid and its sodium, calcium and potassium salts
E 306	Tocopherol-rich extract
E 307	Alpha-tocopherol
E 308	Gamma-tocopherol
E 309	Delta-tocopherol

2. **Emulsifiers, stabilisers, gelling agents E 322, E 400-E 419; E 422-E 495; E 1401-E 1451 shall be evaluated by 31.12.2016**

With higher priority within this group on:

E 483	Stearyl tartrate
E 491-495	Sorbitan esters
E 431	Polyoxyethylene (40) stearate
E 432-436	Polysorbates
E 444	Sucrose acetate isobutyrate
E 481	Sodium stearoyl-2-lactylate
E 482	Calcium stearoyl-2-lactylate
E 414	Acacia gum (gum arabic)[(12)]
E 410	Locust bean gum[(12)]
E 417	Tara gum[(12)]
E 422	Glycerol
E 475	Polyglycerol esters of fatty acids

3. **E 551 Silicon dioxide, E 620-625 Glutamates, E 1105 Lysozyme and E 1103 Invertase shall be evaluated by 31.12.2016**

4. **The remaining food additives other than colours and sweeteners shall be evaluated by 31.12.2018**

With higher priority on

E 552	Calcium silicate
E 553a	Magnesium silicate and trisilicate
E 553b	Talc
E 558	Bentonite
E 999	Quillaia extract
E 338-343	Phosphoric acid and phosphates
E 450-452	Di-, tri- and polyphosphates
E 900	Dimethyl polysiloxane
E 912	Montan acid esters
E 914	Oxidised polyethylene wax
E 902	Candellila wax
E 904	Shellac

E 626-629	Guanylic acid, Disodium guanylate, Dipotassium guanylate and Calcium guanylate
E 630-633	Inosinic acid, Disodium inosinate; Dipotassium inosinate and Calcium inosinate
E 634-635	Calcium 5'-ribonucleotides and Disodium 5'-ribonucleotides
E 507-511	Hydrochloric acid, Potassium chloride, Calcium chloride, Magnesium chloride
E 513	Sulphuric acid

(**1**) OJ L 354, 31.12.2008, p. 16.

(**2**) COM(2007) 418 final.

(**3**) COM(2001) 542 final.

(**4**) Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002:560.

(**5**) Guidance on submissions for food additive evaluations by the Scientific Committee on Food. Opinion expressed on 11 July 2001. SCF/CS/ADD/GEN/26 final.

(**6**) OJ L 237, 10.9.1994, p. 3.

(**7**) OJ L 237, 10.9.1994, p. 13.

(**8**) OJ L 61, 18.3.1995, p. 1.

(**9**) Currently the Opinion expressed by the SCF on 11 July 2001. SCF/CS/ADD/GEN/26 Final.

(**10**) OJ L 354, 31.12.2008, p. 16.

(**11**) OJ L 145, 31.5.2001, p. 43.

(**12**) All natural gums E 400-418 and E 425 could be evaluated at the same time.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 257/2010.